IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC. AND ABBOTT BIOTECHNOLOGY LTD., Plaintiffs, v. CENTOCOR ORTHO BIOTECH, INC. AND CENTOCOR BIOLOGICS, LLC., Defendants.	)	**Civil Action No. 4:09-cv-11340-FDS**

DECLARATION OF BRUCE H. STONER, JR.

I. Introduction

1. I have been retained as an expert in this case by the Plaintiff Abbott in order to address certain issues of patent law and procedure as they relate to the parties' construction of the term "additional agent."

II. Qualifications and Professional Experience

2. I am currently of Counsel at the law firm of Greenblum & Bernstein P.L.C.

3. I am a former Chief Administrative Patent Judge of the Board of Patent Appeals and Interferences ("BPAI") of the United States Patent and Trademark Office ("USPTO"). The BPAI is an administrative tribunal within the USPTO that reviews appeals filed by patent applicants who have received final rejections from Patent Examiners, and decides questions of

patentability and priority of invention in patent interferences. Patent interferences are special proceedings that are conducted by the BPAI according to a unique set of specialized rules. As an Administrative Patent Judge and Chief Judge, I served on numerous panels that reviewed interference proceedings and appeals from final rejections. I also previously served as a Primary Patent Examiner and Supervisory Patent Examiner at the USPTO. My service at the USPTO spanned a period of thirty-three years in total.

4. A copy of my curriculum vitae is attached as Exhibit A.

III. Materials Reviewed

5. In the course of preparing this Declaration, I reviewed the following materials: Abbott's U.S. Patent No. 7,505,485 (the '485 patent); Abbott's U.S. Patent No. 6,914,128 (the '128 patent); the prosecution history of Abbott's '485 patent; the file of Interference 105,592, including the declaration of interference and the claims from Centocor Patent Application No. 10/912,994 (the '994 application) that were involved in Interference No. 105,592; Centocor's opening claim construction brief; Abbott's reply claim construction brief; Centocor's Markman slides 17 and 18 relating to the construction of the term "additional agent;" and Abbott's Markman slides 41-58 relating to the construction of the term "additional agent.

IV. Analysis

6. It is a fact that the USPTO declared an interference between certain claims of Abbott's '128 patent and certain claims of Centocor's '994 application. *See* '128 patent prosecution history, Declaration of Interference, dated December 12, 2007 (attached as Exhibit 1 to the Decl. of Robert J. Gunther, Jr., dated Nov. 19, 2010 ("Gunther Decl.")).

7. It is also a fact that the USPTO did not declare an interference between the claims of Centocor's '994 application and the claims of Abbott's '485 patent. *See* '485 patent

prosecution history, Notice of Allowability, mailed December 29, 2008 (Gunther Decl. Ex. 2) at 3.

8. Centocor argues that because claims of Abbott's '128 patent were found to interfere with Centocor's '994 application, and because Abbott amended the claims of its '485 application to include subject matter that the Examiner had indicated would not interfere with the claims of Centocor's '994 application, Abbott effectively amended the claims of its '485 patent so that they would exclude subject matter defined in the claims of its own '128 patent.

9. Further, Centocor argues that because claim 64 of Abbot's '128 patent and claim 1 of Abbott's '485 patent differ by the inclusion of the term "pharmaceutically acceptable carrier" in '128 claim 64 and the term "additional agent" in '485 claim 1, for these two claims to be "patentably distinct" from each other, the term "additional agent" must exclude "pharmaceutically acceptable carriers." *See* Centocor's Opening Br. at 15, 17-19; *see also* slides 17-18 from Centocor's Markman Presentation (Gunther Decl. Ex. 9).

A. Centocor's assertion that Abbott amended the claims of the '485 patent to make them patentably distinct from the claims of its own '128 patent has no foundation.

10. Abbott's '128 and '485 patents have identical inventors and are owned by the same entity – Abbott. Patent claims having identical inventors cannot interfere with one another as a matter of law. *See* 35 U.S.C. 102(g)(1). As a matter of practice, the USPTO does not declare or continue interferences in applications that are commonly owned. *See* 37 C.F.R. § 41.206. A Patent Examiner would never conduct a comparison between the claims of two patents, or a patent and a patent application, that had identical inventors to determine if the claims interfere with one another. Similarly, a Patent Examiner would never indicate to a patent applicant that the claims of one patent application should be amended to make them not interfere with the claims of a different patent application that had identical inventors.

11. The question of whether the claims of two patents or applications that have identical inventors and are owned by the same entity are patentable over one another is determined under the law of "double patenting" and not under interference law. The USPTO has long instructed its examiners that in a case where the inventive entities of two applications (or an application and a patent) are identical or where the applications (or application and patent) are commonly assigned, even though the inventors are not identical, the question is one of double patenting, and not interference. In this connection, see MPEP 8th Edition, rev. 7, § 804 (July 2008), the version of the MPEP in effect when the examiner passed the '485 patent to issue, especially the charts at pages 800-13, 800-15 and 800-16. Those charts demonstrate that only when there is no common assignee or inventor is it appropriate to resolve a question of "conflicting claims" by interference. *See also, e.g., Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

12. When faced with two patent applications, or a patent and a patent application, that have the same inventors and are commonly owned, and that the Patent Examiner believes are not separately patentable, the Examiner will issue a "double-patenting" rejection. *See* MPEP § 804. Indeed, that is precisely what happened in the present case. During prosecution the Patent Examiner rejected the claims of Abbott's '485 patent as unpatentable over the claims of Abbott's '128 patent under the doctrine of "obviousness-type double patenting." *See* '485 patent prosecution history, Office Action of June 4, 2007 (Gunther Decl. Ex. 3) at 12.

13. An "obviousness-type double patenting" rejection can be overcome either by amending the claims of the pending application to distinguish them over the claims of the commonly owned patent, or by filing a "Terminal Disclaimer."

14. During prosecution of the '485 patent Abbott did not amend the claims to overcome the "obviousness-type double patenting" rejection. Rather, instead of amending the claims to distinguish them from the claims of the '128 patent, Abbott filed a Terminal Disclaimer. *See* '485 patent prosecution history, Terminal Disclaimer of April 22, 2008 (Gunther Decl. Ex. 4). A terminal disclaimer acts to shorten the term of the patent that issues from the later-filed application. *See In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) ("A patent may still issue if an applicant faced with [a double patenting] rejection were to file a terminal disclaimer under 35 U.S.C. § 253, disclaiming "any terminal part of the term ... of the patent," thereby guaranteeing that the second patent would expire at the same time as the first patent."). It has no impact on the scope of the claims. *See Motionless Keyboard Co. v. Microsoft Corp*., 486 F.3d 1376, *1385 (Fed. Cir. 2007) ("A terminal disclaimer simply is not an admission that a later-filed invention is obvious").

B. Even if Abbott had added the "additional agent" limitation to the '485 claims to make them not interfere with claims reciting a "pharmaceutically acceptable carrier" in the '128 Patent, this would not mean that the term "additional agent" must exclude "pharmaceutically acceptable carriers."

15. As set forth above, there can be no interference between two patents, or a patent and a patent application that are commonly owned and have the same inventors. Thus, a patent applicant would never amend a claim in one patent application in order to make it not interfere with a claim in a separate patent or application that is commonly owned and has the same inventors.

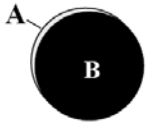
16. However, assuming *arguendo* that such an amendment were made, and as a result the two commonly owned claims did not interfere, the only conclusion that could be drawn would be that the two claims did not satisfy the "two-way test" for interference. *See* 37 C.F.R. § 41.203(a), which replaced 37 CFR § 1.601, effective September 13, 2004, and adopted an

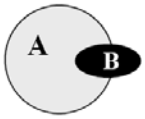
interpretation endorsed by the Federal Circuit in *Eli Lilly & Co., v. Board of Regents of the University of Washington,* 334 F.3d 1264, 1273 (Fed. Cir 2003).

17. According to the two-way test, an interference exists if the subject matter of a claim of party A would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party B and vice versa.

18. Conversely, if either prong of the two way test fails, that is, if the subject matter of a claim of either party A or B would not have anticipated or rendered obvious the subject matter of a claim of the opposing party, then the two-way test is not satisfied and there is no interference.

19. There are various different ways in which a claim A can be separately patentable from a claim B. For example, claim A can be separately patentable from claim B if the two claims do not overlap in scope at all, for example if A excludes B. However, it is also well established that a claim A can be separately patentable from a claim B if claim B is a "species" that falls entirely within the scope of a broader "genus" A. *Id.* at 1268-1270. *See also Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.,* 246 F.3d 1368, 1380 (Fed. Cir. 2001). Some of the different ways in which a claim A can be separately patentable from a claim B are illustrated graphically below:

<table>
<tr><th>INTERFERING</th><th>NOT INTERFERING</th></tr>
<tr><td>Same Patentable Subject Matter
Not Patentably Distinct
 
</td><td>Not Same Patentable Subject Matter
Patentably Distinct
 

Scenario 1 – A <u>excludes</u> B
 

Scenario 2 – A <u>overlaps with</u> B
 

Scenario 3 –A <u>encompasses</u> B
(genus/species)</td></tr>
</table>

20. Thus, even if Abbott had added the "additional agent" limitation to the claims of the '485 patent in order to make those claims not interfere with a claim in Abbott's '128 patent that recited the term "pharmaceutically acceptable carrier," this would not mean that claims reciting the term "additional agent" could not overlap in scope with claims reciting the term "pharmaceutically acceptable carrier." Rather, such claims could be patentably distinct, and thus not interfere, even if the term "pharmaceutically acceptable carrier" constituted a species that fell entirely within the larger genus "additional agents."

21. For the above reasons, I find nothing in the prosecution history of the '485 that supports a conclusion that the term "additional agent" <u>excludes</u> "pharmaceutically acceptable carriers."

V. Trial Exhibits

22. If called as a witness at trial, I may rely on visual aids and demonstrative exhibits that demonstrate the bases of my opinions. Examples of these visual aids and demonstrative exhibits may include, for example, claim charts, patent drawings, excerpts from patent specifications, file histories, interrogatory responses, deposition testimony and deposition exhibits, as well as charts, diagrams, videos and animated or computer-generated video.

VI. Compensation

23. I am compensated for my time at the rate of $600 for each hour of service that I provide in connection with this case. That compensation is not contingent upon my performance, the outcome of the case, or any issues involved in or related to this case.

VII. Previous Testimony

24. A list of the cases in which I have provided testimony as an expert witness is attached to this report, as part of my curriculum vitae, at Exhibit A.

VIII. Supplementation of Opinions

25. I reserve the right to adjust or supplement my analysis in light of any critique of or comments on my report or alternative opinions advanced by or on behalf of Abbott.

26. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November 19, 2010

Bruce H. Stoner, Jr. Esq.

CERTIFICATE OF SERVICE

I certify that, on November 19, 2010, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Robert J. Gunther, Jr.